

Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 1, 6, 7, 9, 10, 13, 18 and 20-29 are pending in the application, with claim 1 being the independent claim.

Based on the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 1, 6, 7, 9, 10, 13, 18 and 20-29 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. (Advisory Action of September 10, 2008; Page 1.) Applicants respectfully disagree and traverse the rejection.

The Examiner has alleged that

Applicants have amended the claims to recite that the composition comprises "one or more peptides eight to thirteen residues in length" and where one of the peptides of the composition is a species selected from Markush group of Claim 1. Applicants' amendment does not overcome the outstanding enablement rejection because the recitation in Claim 1 "CTL epitope" impliedly requires that each peptide actually possess the inherent property of being T-cell specific and CTL immunogenic and further as defined in the specification as having MHC binding ability. Applicants have not demonstrated the genus of peptides falling within the recited size range for peptides possessing all of the required properties in order to be a "CTL epitope."

(*See Id.*)

As an initial matter, Applicants note that the claims previously rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement

requirement (claims 5, 8, 11, and 12) were cancelled without prejudice to or disclaimer of the subject matter therein, and therefore that the outstanding enablement rejection has thereby been rendered moot. While the outstanding enablement rejection did not apply to the currently pending claims, Applicants assert, for the reasons presented below, that claims 1, 6, 7, 9, 10, 13, 18 and 20-29 are adequately enabled.

"As concerns the breadth of a claim relevant to enablement, the only relevant concern should be whether the scope of enablement provided to one skilled in the art by the disclosure is commensurate with the scope of protection sought by the claims." MPEP § 2164.08 (2006) (citing *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244 (Fed. Cir. 2003); *In re Moore*, 439 F.2d 1232, 1236 (C.C.P.A. 1971); *see also Plant Genetic Sys., N.V. v. DeKalb Genetics Corp.*, 315 F.3d 1335, 1339 (Fed. Cir. 2003).

Applicants note that as long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. § 112 is satisfied. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Additionally, "a specification disclosure which contains a teaching of the manner and process of making and using the invention . . . must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied upon for enabling support." *Rasmusson v. Smithkline Beecham Corp.*, 413 F.3d 1318, 1323 (Fed. Cir. 2005) (quoting *In re Marzocchi*, 439 F.2d 220, 223 (C.C.P.A. 1971)).

Applicants point out that the specification discloses that numerous peptides encompassed by the claimed composition are demonstrated to be CTL epitopes. The specification describes that "Class I molecule binding peptides [CTL peptides] typically

are about 8 to 13 amino acids in length" (Specification, ¶ 38.) Furthermore, the specification describes the binding affinity of hundreds of such peptides: Tables 12, 14, 16, 18, 20, 22, and 24 describe the determined binding affinity of each listed peptide (of which hundreds are listed) to three or more different Class I MHC alleles. Each of the peptides listed in these Tables are about 8 to 13 amino acid residues in length. For example, Table 12 describes that the binding affinity of the peptide LTDIEITCVY to the HLA alleles A*1101, A*2902, and A*3002 is 12, 540 and 80 nM, respectively. The peptide LTDIEITCVY is recited in claim 1 and is ten amino acids in length. The LTDIEITCVY peptide is one of numerous peptides listed in Tables 12, 14, 16, 18, 20, 22, and 24 as demonstrated to bind to several Class I MHC alleles. Thus, the specification demonstrates hundreds of representative examples of peptides falling within the recited range that have MHC Class I binding ability and therefore are demonstrated to be CTL epitopes.

In addition, the specification further discloses how to make and use compositions comprising the elected peptides and how to test these compositions for binding affinity using various assays. (Specification, ¶ 55-59.) The specification also discloses how to test these compositions for inhibition of CTL recognition using purified MHC molecules and radioiodonated peptides and/or cells by immunofluorescent staining and flow microfluorometry, or peptide-dependent class I assembly assays. (Specification, ¶ 77.) The specification also discusses the use of mutant mammalian cell lines to test for the capacity of compositions comprising a particular peptide to induce *in vitro* primary CTL responses. (Specification, ¶ 78.) Additionally, the specification discloses how such compositions can be made. (*See* Specification, ¶ 61-75.)

Thus, as discussed above, the specification not only discloses how to make and use compositions comprising Applicants' elected peptides, the specification also teaches how to assay the efficacy of such compositions and determine whether the particular peptides have the capacity to bind to certain MHC molecules and/or have the ability to induce an immune response. Thus, the specification discloses "at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim."

The purpose of the requirement that the specification describe the invention in such terms that one skilled in the art can make and use the claimed invention without undue experimentation (*i.e.*, the enablement requirement) is to ensure that the invention is communicated to the interested public in a meaningful way. Here, Applicants respectfully assert that the information contained in the disclosure of the specification is sufficient to inform those skilled in the relevant art how to both make and use the claimed invention in a manner that satisfies the requirements of 35 U.S.C. § 112, first paragraph for enablement.

The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), *aff'd. sub nom.*, *Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985). See also *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. Here Applicants respectfully assert that not only is no experimentation necessary to practice the claimed invention, but even if any experimentation was performed it would not be undue as it would be of the type typically engaged in by artisans in this art.

Applicants further note that the Examiner's comments that "Applicants have not demonstrated the genus of peptides falling within the recited size range for peptides possessing all of the required properties in order to be a 'CTL epitope'" appears to correspond to a rejection of the claims under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement of this statute.

The test for the written description requirement is whether one skilled in the art can reasonably conclude that the inventor has possession of the claimed invention in the specification as filed. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991); MPEP § 2163.02. The Federal Circuit has re-emphasized the well-settled principle of law that "[t]he written description requirement does not require the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [they] invented what is claimed.'" *Union Oil of Cal. v. Atlantic Richfield Co.*, 208 F.3d 989, 54 U.S.P.Q.2d 1227 (Fed. Cir. 2000). Furthermore, an applicant is not required to explicitly describe the subject matter. *Unocal*, 208 F.3d at 1000; *see also* MPEP § 2163.02 ("The subject matter of the claim need not be described literally (*i.e.*, using the same terms or *in haec verba* in order for the disclosure to satisfy the description requirement.").

In particular, the Federal Circuit stated in *Univ. of Calif. v. Eli Lilly & Co.*, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997), that:

A description of a genus of cDNAs may be achieved by means of a recitation of [1] a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or [2] of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus . . . We will not speculate in what other ways a broad genus of genetic material may be properly described . . .

Univ. of Cal., 43 U.S.P.Q.2d at 1406. Thus, the Federal Circuit has stated that the written description requirement for a claim directed to a genus of molecules may be satisfied by providing the sequences of a representative number of molecules which fall within the scope of the genus. *See id.*

Applicants assert that, in view of the discussion above, the specification has described hundreds of representative examples of peptides falling within the scope of the claimed genus. Therefore, Applicants assert that even assuming that the rejection of claims 1, 6, 7, 9, 10, 13, 18 and 20-29 was a written description rejection under 35 U.S.C. § 112, first paragraph, that the pending claims have been adequately described and comply with both the written description and enablement requirements of 35 U.S.C. § 112, first paragraph. Thus, Applicants respectfully request that the Examiner reconsider and withdraw the outstanding rejection.

Other Matters

Applicants thank the Examiner for noting that Applicants' previous reply has overcome the rejection of claims 1, 5-13, 18 and 20-29 under 35 U.S.C. § 112, first paragraph, written description.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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